
चिकित्सीय वस्त्रादि — चादर और
तकिए का गिलाफ़ — विशिष्टि

Medical Textiles — Bedsheet and
Pillow Cover — Specification

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FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Technical Textiles for Medtech Applications Sectional Committee had been approved by the Textiles Division Council.

Bedsheets and pillow covers are useful in providing an aid to infection control in hospitals and nursing homes.

The composition of the Committee responsible for the formulation of this standard is given in Annex B.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

*Indian Standard***MEDICAL TEXTILES — BEDSHEET AND
PILLOW COVER — SPECIFICATION****1 SCOPE**

1.1 This standard specifies the requirements for single use and reusable bedsheet and pillow cover set intended for medical use.

1.2 The bedsheet and pillow cover set conforming to this standard may be supplied in sterile or unsterile condition as per the agreement between the buyer and the seller.

1.3 This standard does not specify the general appearance, feel, shade, etc, of the bedsheet and pillow cover.

2 REFERENCES

The standards listed in Annex A contain provisions which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated in Annex A.

3 TERMS AND DEFINITIONS

For the purpose of this standard, the following terms shall apply.

3.1 Cleanliness-Microbial — Freedom from population of viable microorganism on a product and/or a package.

3.2 Colony Forming Unit (CFU) — Unit by which culturable number of microorganisms is expressed.

3.3 Manufacturer — Natural or legal person with responsibility for the processing of raw material or inputs in any manner that results in the emergence of a new product having a distinct name, character and use.

3.4 Reusable Product — Product intended by the manufacturer to be reprocessed and reused.

3.5 Single-use Product — Product intended by the manufacturer to be used only once.

4 MANUFACTURE

The bedsheet and pillow cover shall be made from spunlace and/or spunbond non-woven fabric or woven fabric; made of cotton or polyester or their blends.

5 WORKMANSHIP AND FINISH

5.1 The bedsheet and pillow cover set shall be clean and free from substances liable to cause tendering during storage. The manufacture and preparation of the bedsheet and pillow cover shall be conducted under proper hygienic conditions. The fabric selvages of bedsheet and pillow cover when visually examined shall be straight and firm.

5.2 The size of bed sheet and pillow cover set shall be as per the agreement between buyer and seller.

6 GENERAL REQUIREMENTS

The fabric used in the manufacture of reusable bedsheet and pillow cover set shall conform to general requirements as specified in Table 1 after declared/maximum wash cycle. The washing of fabric shall be done as per procedure 5 A given in IS 15370 and tumble drying shall be done as per procedure E of IS 15370.

Table 1 Colour fastness and Dimensional Stability Requirement of Fabric (for Reusable)
(Clause 6)

SI No.	Characteristic	Requirement	Method of Test, Ref to
(1)	(2)	(3)	(4)
i)	Colour fastness to rubbing		IS/ISO 105-X 12
	a) Dry	4 or better	
	b) Wet	4 or better	
ii)	Colour fastness to perspiration (acidic and alkaline)		IS/ISO 105-E04
	a) Colour change	4 or better	
	b) Staining	4 or better	
iii)	Colour fastness to washing		IS/ISO 105-C06
	a) Colour change	4 or better	
	b) Staining	4 or better	
iv)	Colour fastness to light		
	Color change	4 or better	IS/ISO 105-B02
v)	Dimensional stability to washing, percentage	IS 15370/ISO 6330	
	Length and width	± 3	
vi)	Pilling resistance	3-4 or better (1000 revolution)	IS 10971 (Part 2)
vii)	Scouring loss, percent, <i>Max</i> (for cotton)	2	IS 1383

Table 2 Requirements for Bedsheet and Pillow Cover Set

(Clause 7.1)

SI No.	Characteristic	Requirement	Method of test, Ref to
(1)	(2)	(3)	(4)
i)	Tensile strength (dry and wet) (N)	≥ 20	Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)
ii)	Bursting strength (dry and wet) (kPa)	≥ 40	IS 1966 (Part 1)
iii)	Seam strength (dry and wet) (N)*	≥ 20	Nonwoven: IS 15891 (Part 18), Woven: IS/ISO 13935 (Part 1)
iv)	pH	6.0-8.0	IS 1390
v)	Water soluble substance, percent, <i>Max</i>	1	IS 14944
vi)	Cleanliness-microbial (CFU/100 cm ²)	≤ 300	ISO 11737-1
vii)	Particle release [log10 (lint count)]	≤ 4.0	IS 15891 (Part 10)
viii)	Biocompatibility Evaluation (<i>see</i> Note 1)		
	a) Cytotoxicity	None	IS/ISO 10993- 5
	b) Irritation and skin sensitization	Non-irritant and non-sensitizer	IS/ISO 10993- 10
ix)	Moisture vapour transmission rate (<i>Max</i>) (<i>optional</i>), (<i>see</i> Note 2)	40 m ² Pa/W	IS 17376

*For pillow cover only.

NOTES

1 Confirm the biocompatibility of raw material at design stage. The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material or source of supply for manufacturing the product.

2 Moisture vapour transmission is the ability of water vapour to pass through a material. This attribute has a significant effect on comfort, because materials without the ability to allow moisture transmission are generally uncomfortable.

7 PERFORMANCE REQUIREMENTS

7.1 The bedsheet and pillow cover set shall conform to the requirements specified in Table 2.

7.2 The performance requirements of reusable products shall have to be met after declared wash and sterilization cycle. The manufacturer shall provide the handling, storage and sterilization instruction for reusable bedsheet and pillow cover set to ensure proper use and care. The washing of product shall be done as per procedure 5 A given in IS 15370 and tumble drying shall be done as per procedure E of IS 15370.

8 PACKAGING AND STERILIZATION

8.1 The bedsheet and pillow cover set shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. Details of the packing shall be as agreed to between the buyer and the seller. Packaging of the product shall be such as to maintain the integrity of the product throughout its shelf life.

8.2 For packaging of the products, requirements as per IS/ISO 11607-1 and 2 shall be followed. For packaging and sterilization, the Medical Device Rule, 2017 shall be followed. Sterilization and validation of sterilization process shall be done as per IS/ISO 11135, IS/ISO 11137-1 and 2, ISO 11138-7, IS/ISO 10993-7 and ISO 17665-1 standards.

9 MARKING

9.1 Each pack of the bedsheet and pillow cover set shall be legibly and indelibly marked with following information:

- a) Name of the product;
- b) Dimension/Size of the product;
- c) Manufacturer's name, initials or trademark, if any;
- d) Month and year of manufacture, batch/lot number;
- e) Sterilized or un-sterilized;
- f) An indication that the product has been specified by the manufacturer for single-use only;
- g) Declared life cycle/maximum wash cycle, if the product is reusable;
- h) Method of sterilization and necessary instructions in the event of damage to sterile packaging and, where appropriate, description of methods of re-sterilization;
- j) An indication that the device has been specified by the manufacturer for single-use only;
- k) If the product is multiple use, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilization and any restriction on the number of reuses. Where

products are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization should be such that, if correctly followed, the device will still comply with "the essential principles of safety and performance of medical devices"; and

- m) Any other requirement as per Medical Device Rules, 2017 or as required by the law in force.

9.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act, 2016* and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

10 SAMPLING AND CRITERIA FOR CONFORMITY

10.1 Lot

All the bedsheet and pillow cover sets of the same material produced under similar conditions of manufacture and/or sterilization shall constitute a lot.

10.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

10.1.2 Unless otherwise agreed, the number of bedsheet and pillow cover sets to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 1, column 2 and column 4 of Table 3.

10.1.3 These bedsheet and pillow cover sets shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

10.2 Number of Tests and Criteria for Conformity

10.2.1 All the bedsheet and pillow cover sets selected as per column 2 of Table 3 shall be examined for workmanship and finish (*see 5.1*).

10.2.1.1 Any bedsheet and pillow cover sets failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements, if the total number of defectives found in the sample is less than or equal to the acceptance number given in column 3 of Table 3. Otherwise, the lot shall be rejected.

10.2.2 Out of the sample already found satisfactory according to **10.2.1.1**, a sub-sample as per column 4 of Table 3 shall be taken. This sub-sample shall be further tested for the remaining requirements.

10.2.3 The lot shall be considered as conforming to the requirements of the specification if the total number of defective products found in the sample (as per **10.2.2**) is less than, or equal to the acceptance number as given in column 5 of Table 3.

Table 3 Number of Bedsheet and Pillow Cover Sets to be Selected*(Clauses 10.1.2, 10.2.1, 10.2.1.1, 10.2.2 and 10.2.3)*

Lot Size	Non-destructive Testing		Destructive Testing	
	No. of Bedsheet and Pillow Cover set to be Selected	Acceptance Number	No. of Bedsheet and Pillow Cover Sets to be Selected	Acceptance Number
N	n	a	n ₁	a ₁
(1)	(2)	(3)	(4)	(5)
Up to 50	5	0	3	0
51 to 150	8	1	5	0
151 to 280	13	1	8	0
281 to 500	20	2	8	0
501 to 1 200	32	3	13	0
1 201 to 3 200	50	5	13	0
3201 and above	80	7	20	1

NOTE — Pillow cover of a set shall be tested for seam strength only as specified in Table 2. Accordingly bedsheet shall be tested for other performance requirements as specified in Table 2.

ANNEX A

(Clause 2)

LIST OF REFERRED INDIAN STANDARDS

<i>IS No./Other Publication</i>	<i>Title</i>	<i>IS No./Other Publication</i>	<i>Title</i>
1383 : 1977	Methods for determination of scouring loss in grey and finished cotton textile materials (<i>first revision</i>)	15891(Part 18) : 2017/ISO 9073-18 : 2007	Textiles — Test methods for nonwovens: Part 18 Determination of breaking strength and elongation of nonwoven materials using the grab tensile test
1390 : 2019	Methods for determination of pH value of aqueous extracts of textile materials (<i>second revision</i>)	IS/ISO105-B02 : 2014	Textiles — Tests for colour fastness: Part B02 Colour fastness to artificial light: Xenon arc fading lamp test
1966 (Part 1) : 2009/ ISO 13938-1 : 1999	Textiles — Bursting properties of fabrics — Determination of bursting strength and bursting distension: Part 1 Hydraulic method (<i>second revision</i>)	IS/ISO 105-C06 : 2010	Textiles — Tests for colour fastness: Part C06 Colour fastness to domestic and commercial laundering
1969 (Part 1) : 2018/ ISO 13934-1 : 2013	Textiles — Tensile properties of fabrics: Part 1 Determination of maximum force and elongation at maximum force using the strip method (<i>fourth revision</i>)	IS/ISO 105-E04 : 2008	Textiles — Tests for colour fastness: Part E04 Colour fastness to perspiration
4905 : 2015	Random sampling and randomization procedures (<i>first revision</i>)	IS/ISO 105-X12 : 2016	Textiles — Tests for colour fastness: Part X12 Colour fastness to rubbing
10971 (Part 2) : 2011/ ISO 12945-2 : 2000	Textiles — Determination of fabric propensity to surface fuzzing and to pilling: Part 2 Modified martindale method (<i>first revision</i>)	17376 : 2020/ ISO 11092 : 2014	Textiles — Determination of physiological effects — Measurement of thermal and water-vapour resistance under steady-state conditions (sweating guarded-hot plate test)
14944 : 2020	Surgical dressings — Methods of test (<i>first revision</i>)	IS/ISO 10993-5 : 2009	Biological evaluation of medical devices: Part 5 Tests for in vitro cytotoxicity
15370 : 2005/ ISO 6330 : 2000	Textiles — Domestic washing and drying procedures for textile testing	IS/ISO 10993-7 : 2008	Biological evaluation of medical devices: Part 7 Ethylene oxide sterilization residuals
15891 (Part 3) : 2011/ ISO 9073-3 : 1989	Textiles — Test methods for nonwovens: Part 3 Determination of tensile strength and elongation	IS/ISO 10993-10 : 2010	Biological evaluation of medical devices: Part 10 Tests for irritation and skin sensitization
15891 (Part 10) : 2017/ISO 9073-10 : 2003	Textiles — Test methods for nonwovens: Part 10 Lint and other particles generation in dry state	IS/ISO 11135 : 2014	Sterilization of health-care products—Ethyleneoxide—Requirements for the development, validation and routine control of a sterilization process for medical devices

IS 17630 : 2021

<i>IS No./Other Publication</i>	<i>Title</i>	<i>IS No./Other Publication</i>	<i>Title</i>
IS/ISO 11137-1 : 2006	Sterilization of health care products — Radiation: Part 1 Requirements for development, validation and routine control of a sterilization process for medical devices	ISO 11138-7 : 2019	Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results
IS/ISO 11137-2 : 2013	Sterilization of health care products — Radiation: Part 2 Establishing the sterilization dose	IS/ISO 13935-1 : 2014	Textiles — Seam tensile properties of fabrics and made-up textile articles: Part 1 Determination of maximum force to seam rupture using the strip method (<i>first revision</i>)
IS/ISO 11607-1 : 2006	Packaging for terminally sterilized medical devices: Part 1 Requirements for materials, sterile barrier systems and packaging systems	ISO 11737-1 : 2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
IS/ISO 11607-2 : 2006	Packaging for terminally sterilized medical devices: Part 2 Validation requirements for forming, sealing and assembly processes	ISO 17665-1 : 2006	Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

ANNEX B*(Foreword)***COMMITTEE COMPOSITION**

Technical Textiles for Medtech Applications, TXD 36

<i>Organization</i>	<i>Representative(s)</i>
The South India Textile Research Association, Coimbatore	DR PRAKASH VASUDEVAN (Chairman)
3 M India Limited, New Delhi	SHRI KULVEEN SINGH BALI SHRIMATI PRABHA HEGDE (<i>Alternate</i>)
Association of Indian Medical Devices (AiMeD), New Delhi	DR G. D. AGARWAL SHRI JITENDRA SACHCHADE (<i>Alternate</i>)
All Indian Institute of Medical Sciences, New Delhi	DR VIJAYDEEP SIDDHARTH DR ANOOP DAGA (<i>Alternate</i>)
Business Coordination House, New Delhi	SHRI SAMEER GUPTA SHRIMATI RITIKA GUPTA (<i>Alternate</i>)
Cologenes Healthcare Pvt Ltd, Salem	SHRI R. KRISHNAKUMAR SHRI K. RAMPRASAD (<i>Alternate</i>)
Defence Research and Development Establishment (DRDE), Gwalior	DR VIKAS B. THAKRE SHRI SURAJ BHARATI (<i>Alternate</i>)
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DGQA (Ministry of Defence), New Delhi	SHRI SENTHIL KUMAR SHRI ARNAB DAS (<i>Alternate</i>)
Director General of Health Services, New Delhi	DR INDER PRAKASH DR SUNNY SWARNKAR (<i>Alternate</i>)
M/s Dispoline India Private Limited, Bengaluru	SHRI SUMIT MARWAH.
Dr Sabharwal Manufacturing Labs Pvt Ltd, Panchkula	SHRI MANISH SABHARWAL SHRI DHARUV SABHARWAL (<i>Alternate</i>)
Federation of Indian Chambers of Commerce & Industry, New Delhi	DR SANJIV REHLAN MS TULSI (<i>Alternate</i>)
Ginni Filaments Limited, Noida	SHRI PRAMOD SHARMA
Govt Medical College and ESI Hospital, Coimbatore	DR N. TAMILSELVEN DR K. KULENDAIVELU (<i>Alternate</i>)
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Indian Technical Textile Association, Mumbai	DR ANUP RAKSHIT MR MAHESH KUDAR (<i>Alternate</i>)
Johnson and Johnson Ltd, Mumbai	SHRI RAM SHUKLA MR VIVEK BANSAL (<i>Alternate</i>)
Kamal Healthcare Pvt Limited, Tamilnadu	SHRI S. SANKAR MARIMUTHU
KOB Medical Textiles Pvt Ltd, Palladam	SHRI ARUN BUCHADE SHRI S. KUMAR SUBRAMANIAN (<i>Alternate</i>)
Livinguard Technologies Pvt Ltd, Mumbai	MS SHIVANI SWAMI DR SHEFALI MISHRA (<i>Alternate</i>)

<i>Organization</i>	<i>Representative(s)</i>
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